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C O N F I D E N T I A L SECTION 01 OF 02 TEL AVIV 002338

SIPDIS

FOR NEA/IPA GLOGERFO AND EB/IPE SWILSON AND AADAMO
DEPARTMENT PLEASE PASS TO USTR ESAUMS AND BPECK
DEPARTMENT PLEASE PASS TO USPTO JURDAB
USDOC FOR 4520/MAS/ANESA/HVINEYARD
USDOC FOR 4521/MAC/ANESA/CLOUSTANAU/NWEIEGLER
USDOC FOR 3131/USFCS/OIO/ANESA/DHARRIS/GLITMAN

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TAGS: [ETRD](#) [KIPR](#) [IS](#) [ECONOMY](#) [AND](#) [FINANCE](#) [LABOR](#) [AND](#) [COMMERCE](#) [ISRAEL](#) [RELATIONS](#)
SUBJECT: GOI TO MOVE FORWARD WITH PATENT TERM EXTENSION
LEGISLATION

Classified By: Charge d'Affaires Gene A. Cretz for reasons 1.4 (b) and (d)

1. (C) Summary. On April 13 local research-based pharmaceutical representatives expressed concern about GOI intentions on the issue of patent term extension legislation. The representatives said that they considered the patent-term extension (PTE) roll-back as direct compensation to the generic industry for their acceptance of the recently approved marketing exclusivity legislation. The industry representatives informed us that contrary to previous GOI statements, the GOI was planning action on Patent Term Extension (PTE) legislation in the next session of the Knesset. Post subsequently confirmed with the GOI their intention to move ahead with PTE legislation in May. End summary.

1 Step Forward, 3 Steps Back

2. (C) In an April 13 meeting with local representatives from research-based drug companies Merck and Pfizer and the local representative of Pharma (PhRMA), Econcouns and Econoff spoke at length about the passage of the marketing exclusivity legislation by the Knesset, and the pending PTE legislation. While admitting that the adoption of marketing exclusivity was an improvement in the protection of IPR in Israel, the reps told Econoffs that the marketing exclusivity legislation will affect only 3% of their products. In contrast, they estimate that more than 90% of pharmaceutical products will be affected by the PTE legislation. In a discussion on the impact of the recently passed marketing exclusivity law, the representatives were unable to predict if the law would deter new pharmaceutical products from being launched in Israel. However, all agreed that a generation of products developed before the implementation date of marketing exclusivity (July 1, 2005) will likely not be introduced in the Israeli market.

So What is a PTE?

3. (C) The representatives provided background information regarding the PTE legislation. First adopted in 1998 as part of what is commonly known as, "The TEVA Bill" the original PTE legislation was based on the U.S. Bolar amendment. At the time the law was adopted, it was intended to balance the needs of research based pharmaceuticals with those of the generic industry. Specifically, since generic companies were allowed to experiment with molecules that were protected by patents, the research based companies were allowed to seek an extension of their patent for commercial purposes. In the analysis of the representatives, because patent term extensions benefit innovations that are not covered by the provisions of the new marketing exclusivity law (such as new indications and new formulations) the roll-back of the PTE has serious consequences for the ability of research-based companies to protect their innovations in Israel.

4. (C) Econcouns queried the company reps about the de facto PTE implementation in Israel. They maintained that from the passage of the law in 1998 until the present time, pharmaceutical companies have been able to choose the country of reference for their patent term extension request. Then based upon the extension provided in the referenced country (for a period of no more than 5 years) the patent is extended in Israel. When the law was passed in 1998 the only country with such a patent term extension program was the United States (and thus the only possible country of reference). Since that time a number of other countries have adopted similar provision, but as the U.S. generally provides for the most generous extension, it is the reference country of choice for companies. The legal opinion of the patent commissioner in July 2003 is therefore de facto a statement that the process will continue as currently implemented, opined local reps.

How Many Bills Does it Take to Pass a Law?

15. (C) In addition to the legislation that will be submitted to the Knesset from the government (based on the ministerial decision of September 13, 2004), a private bill sponsored by 10 members of the Knesset has been introduced. The texts of the two laws are identical. Yair Shiran, Director of International Agreements at the Ministry of Industry, Trade, and Labor (MOITL) told Econoff on April 14 that the GOI is, "moving forward with the legislation and our plan to clarify the patent-term extension." Shiran claimed that he would be surprised if action is taken before Passover (Note: The Knesset is already in recess for the Passover holiday and will not resume regular session until May 16. End note.) Shiran said that the GOI is ready to continue discussion with USTR on the law and could make amendments to the legislation. However, Shiran emphasized that the GOI needed to pursue the legislation and indicated no intention to delay its consideration. In order to provide a real alternative to the duplicate government legislation and private bill, the research-based companies have drafted legislation that supports the rights of companies to choose a country to reference in the application for a PTE. Thus, they reason, the GOI will have to make a clear policy choice and cannot simply claim that no alternative plan was offered. In total, three laws on PTE will be considered by the Knesset sometime after the Passover recess.

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